DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-264/S-022

Procter & Gamble
Health Care Research Center
8700 Mason-Montgomery Road
P.O. Box 8006
Mason, Ohio 45040-9492

Attention: Wendy M. Sauber
Section Head, US Regulatory Affairs

Dear Ms. Sauber:

Please refer to your supplemental new drug application dated August 9, 2001, received August 10, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dantrium Intravenous (dantrolene sodium for injection).

We acknowledge receipt of your submission dated September 14, 2001.

This "Changes Being Effected" supplemental new drug application provides revised labeling (package insert) that includes a Geriatric Use subsection in compliance with 21 CFR 201.57(f)(10), "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of 'Geriatric Use' Subsection in the Labeling."

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Cynthia McCormick

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